UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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| UNITED STATES OF AMERICA *ex rel.* VEN-A-CARE OF THE FLORIDA KEYS, INC., a Florida Corporation, by and through its principal officers and directors, ZACHARY T. BENTLEY, T. MARK JONES,<br><br>Plaintiffs,<br><br>v.<br><br>DEY, INC., DEY L.P., INC., and DEY L.P.,<br><br>Defendants. | Civil Action No. 05-11084-MEL (Consolidated with certain claims severed from Civil Action No. 00-10698-MEL)<br>**FILED IN CAMERA AND UNDER SEAL** |

**UNITED STATES' COMPLAINT**

The United States brings this action to recover losses sustained by the Medicare and Medicaid programs as a result of the sustained efforts of the defendants Dey, Inc., Dey L.P., Inc., and Dey L.P. (collectively, "Dey") to defraud these programs. Over the course of a number of years, Dey has reported inflated drug prices knowing that Medicare and Medicaid would rely on those prices to set reimbursement rates for Dey's pharmaceutical products. Dey's actual sales prices for its pharmaceutical products were and are far less than the prices reported by Dey. By knowingly reporting fraudulently inflated prices – sometimes 1000% higher than Dey's actual prices – Dey has ensured that its retail customers and other providers who dispense its drugs received inflated reimbursement and profits from Medicare and Medicaid. Dey has used the public fisc as a marketing tool, actively promoting the government-funded "spread" between

(1) its fraudulently inflated prices and (2) its actual sales prices as an inducement to its customers. These efforts have allowed Dey to increase its profits by boosting sales for its drugs.

## I. NATURE OF ACTION

1. The United States brings this action to recover treble damages and civil penalties under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-33, and to recover damages and other monetary relief under the common law or equitable theories of fraud and unjust enrichment.

2. The United States bases its claims on Dey having caused the submission of false or fraudulent claims to the United States in violation of 31 U.S.C. § 3729(a)(1), and having made and used false statements to get false or fraudulent claims paid by the United States in violation of 31 U.S.C. § 3729(a)(2).

3. Dey has engaged in a fraudulent scheme that has caused the Medicare and Medicaid programs to pay excessive reimbursement to Dey's customers, including pharmacies, homecare pharmacies, and other purchasers of Dey products. In furtherance of this scheme, Dey reported false, fraudulent and inflated drug prices for certain drugs (listed in paragraph 29 below) to several price reporting compendia that the Medicare and Medicaid programs relied upon to set reimbursement rates for Dey's customers. A chart showing examples of the differences between the prices at which Dey actually has sold its drugs and the false prices reported by Dey is attached as Exhibit A. At all relevant times, Dey knew that the Medicare and Medicaid programs relied on Dey's reported prices to those compendia to set reimbursement rates for claims submitted for Dey's drugs. Dey then sold its drugs for far lower prices, and marketed to existing and potential customers the government-funded "spread" between the

inflated reimbursement amounts and the actual acquisition costs of the drugs to boost Dey's sales and profits.

4. At all relevant times, Dey knew that its false price reporting and marketing efforts would cause its customers to submit claims for fraudulently inflated Medicare and Medicaid reimbursement.

5. Dey's fraudulent scheme to induce customers to purchase its products by ensuring that federal and state reimbursement rates for those products would be set at artificially inflated levels violated the FCA, the federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b), common law and numerous state laws.

6. In order to get fraudulent claims paid by the United States, Dey also routinely made false statements directly to state Medicaid programs by reporting these same fraudulently inflated prices to the states. These statements violated the FCA, common law and various state laws.

7. The United States timely asserts the causes of action alleged herein based on the filing of relator's complaint in this action.

## II. JURISDICTION

8. The Court has subject matter jurisdiction to entertain this action under 28 U.S.C. §§ 1331 and 1345 and supplemental jurisdiction to entertain the common law causes of action pursuant to 28 U.S.C. § 1367(a). The Court may exercise personal jurisdiction over Dey pursuant to 31 U.S.C. § 3732(a) because Dey transacts business in the District of Massachusetts.

## III. VENUE

9. Venue is proper in the District of Massachusetts under 31 U.S.C. § 3732 and 28 U.S.C. § 1391(b) and (c) because Dey has transacted business in this District.

## IV. PARTIES

10. The United States brings this action on behalf of the Department of Health and Human Services ("HHS") and the Centers for Medicare & Medicaid Services ("CMS") (formerly known as the Health Care Financing Administration), which administer the Medicare and Medicaid programs.

11. Relator Ven-A-Care of the Florida Keys, Inc. ("Ven-A-Care"), is a corporation organized under the laws of Florida, with its principal offices in Key West, Florida. Ven-A-Care is a pharmacy licensed to provide prescription drugs specified in this Complaint and has been, during the relevant period of this Complaint, a Medicare and Florida Medicaid provider. Ven-A-Care's principal officers and/or directors during the relevant time period have included John M. Lockwood, M.D., Zachary Bentley, Luis Cobo and T. Mark Jones, who are each citizens of the United States and reside in Key West, Florida. The FCA, 31 U.S.C. § 3730(b)(1), provides that private parties may bring a lawsuit on behalf of the United States to recover damages for false claims. Ven-A-Care brought this action against Dey on behalf of itself and the United States.

12. Defendant Dey, Inc. is a corporation organized under the laws of Delaware with its principal offices in Napa, California. Prior to June 30, 1998, Dey, Inc. was known as "Dey Laboratories, Inc."

13. Defendant Dey L.P., Inc. is a corporation organized in 1993 under the laws of Delaware with its principal offices in Napa, California. Prior to June 30, 1998, Dey L.P., Inc.

was known as "Dey Laboratories L.P., Inc." Upon information and belief, Dey L.P., Inc. is wholly owned by Dey, Inc. Pursuant to rule 15(c) of the Federal Rules of Civil Procedure, the claims against Dey L.P., Inc. relate back to the dates of the original pleadings in these consolidated cases.

14. Defendant Dey L.P. is a limited partnership organized in 1993 under the laws of Delaware. Prior to June 30, 1998, Dey L.P. was known as "Dey Laboratories L.P.." Upon information and belief, the general partner of Dey L.P. is Dey, Inc., and the sole limited partner of Dey L.P. is Dey L.P., Inc., which owns 99 percent of the assets of Dey L.P. Pursuant to rule 15(c) of the Federal Rules of Civil Procedure, the claims against Dey L.P. relate back to the dates of the original pleadings in these consolidated cases.

15. At all times material to this action, Dey has transacted business in the District of Massachusetts by, including but not limited to, selling and distributing its drugs, including those identified in this Complaint, to purchasers within the District of Massachusetts.

## V. THE LAW

### A. The False Claims Act

15. The FCA provides in pertinent part, that:

> (a) Any person who (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; (3) conspires to defraud the Government by getting a false or fraudulent claim paid or approved by the Government . . . .
>
> * * *
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the

> amount of damages which the Government sustains because of the act of that person . . . .
>
> (b) For purposes of this section, the terms "knowing" and "knowingly" mean that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.

31 U.S.C. § 3729.

16. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 (notes), and 64 Fed. Reg. 47099, 47103 (1999), the civil penalties were adjusted to $5,500 to $11,000 for violations occurring on or after September 29, 1999.

**B. The Federal Anti-Kickback Statute**

17. Congress first enacted the federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b), in 1972 to protect the integrity of the Medicare and Medicaid programs. Congress strengthened the statute in 1977, and again in 1987, to ensure that kickbacks masquerading as legitimate transactions would not evade its reach. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

18. The anti-kickback statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for federally-funded medical items, including items provided under the Medicare and Medicaid programs. In pertinent part, the statute provides:

> (b) Illegal remuneration
>
> * * *
>
> (2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person --
>
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b). Those who violate the statute also are subject to exclusion from participation in federal health care programs and, effective August 6, 1997, civil monetary penalties of up to $50,000 per violation and up to three times the amount of remuneration paid. 42 U.S.C. §§ 1320a-7(b)(7) and 1320a-7a(a)(7).

## VI. THE FEDERAL HEALTHCARE PROGRAMS

16. The Medicare and Medicaid programs were created in order to provide access to healthcare for elderly, indigent or disabled residents of the United States.

### A. The Medicaid Program

17. Medicaid is a joint federal-state program that provides health care benefits for certain groups, primarily the poor and disabled.

18. The federal Medicaid statute sets forth the minimum requirements for state Medicaid programs to qualify for federal funding. 42 U.S.C. § 1396a.

19. The federal portion of states' Medicaid payments, known as the Federal Medical Assistance Percentage ("FMAP"), is based on a state's per capita income compared to the national average. 42 U.S.C. § 1396d(b). Among the states, the FMAP is at least 50%, and as high as 83%.

20. The Medicaid statute requires each participating state to implement a plan containing certain specified minimum criteria for coverage and payment of claims. 42 U.S.C. §§ 1396, 1396a(a)(13), 1396a(a)(30)(A).

21. The Medicaid programs of all states reimburse for prescription drugs.

22. The vast majority of states award contracts to private companies to evaluate and process Medicaid recipients' claims for payment. Typically, after processing the claims, these private companies then generate funding requests to the state Medicaid program, which in turn obtains federal funds from the United States.

23. By becoming a participating supplier in Medicaid, suppliers agree to abide by all laws, regulations, and procedures applicable to that program, including those governing reimbursement.

**B. The Medicare Program**

24. In 1965, Congress enacted Title XVIII of the Social Security Act, known as the Medicare program, to pay for the costs of certain healthcare services and items. Entitlement to Medicare is based on age, disability or affliction with end-stage renal disease. 42 U.S.C. §§ 426-426a, 1395o.

25. HHS is responsible for the administration and supervision of the Medicare program. CMS is an agency of HHS and directly administers the Medicare program. The Medicare program has several parts, including Medicare Part B ("Supplementary Medical Insurance for the Aged and Disabled"), which covers physician services, as well as durable medical equipment ("DME") and certain drug products and supplies. 42 U.S.C. § 1395k; 42 C.F.R. § 410.10.

26. Medicare Part B generally covers drugs which are provided either: (a) incident to a physician's service and cannot usually be self-administered (42 C.F.R. § 410.26 (e.g., certain oncology drugs)); or (b) in conjunction with the medical necessity of an infusion pump or nebulizer or other DME device payable under Medicare's DME benefit. 42 C.F.R. §§ 405.517, 414.701.

27. During the relevant time period, CMS contracted with private insurance carriers ("Contractors") to administer and pay Part B claims from the Medicare Trust Fund. 42 U.S.C. § 1395u. In this capacity, the Contractors act on behalf of CMS. 42 C.F.R. § 421.5(b).

28. Contractors receive, process and pay claims under Medicare Part B for drugs from various Medicare providers and suppliers. Typically, once a contractor approves a claim, the contractor then submits a payment request to a Medicare bank account funded by federal funds.

**C. Drug Reimbursement Under Medicaid and Medicare**

29. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-97, requires pharmaceutical companies to submit to the Food and Drug Administration ("FDA") a listing of every drug product in commercial distribution. 21 U.S.C. § 355. The FDA provides for the assignment to each listed drug product of a unique 11-digit, 3-segment number, known as the

National Drug Code ("NDC"). FDA has assigned approximately 170,000 NDCs to drug products. The drugs and corresponding NDCs at issue in this case are listed below:

| Description | NDC number |
|---|---|
| Albuterol Inhalation Aerosol Metered-Dose Inhaler, 17g | 49502-0303-17 |
| Albuterol Inhalation Aerosol Metered-Dose Inhaler, 17g | 49502-0333-17 |
| Albuterol Inhalation Aerosol MDI Refill, 17g | 49502-0303-27 |
| Albuterol Inhalation Aerosol MDI Refill, 17g | 49502-0333-27 |
| Albuterol Sulfate Inhalation Solution .5% 5mg/ml Size, 20mL MD | 49502-0196-20 |
| Albuterol Sulfate .5% (Sterile) 20mL MD | 49502-105-01 |
| Albuterol Sulfate Unit Dose, 0.083% inhalation solution, package of 25, 2.5 mg/3ml | 49502-697-03, J7620 |
| Albuterol Sulfate Unit Dose, 0.083% inhalation solution, package of 30, 2.5 mg / 3 ml | 49502-697-33 |
| Albuterol Sulfate Unit Dose, 0.083% inhalation solution, package of 60, 2.5 mg 3 ml | 49502-697-60 |
| Cromolyn Sodium Inhalation Solution 20 mg/2 ml, unit dose vials, 120s | 49502-0689-12 |
| Cromolyn Sodium, Inhalation Solution 20 mg/2 ml, unit dose vials, 60s | 49502-0689-02, J7630 |
| Ipratropium Bromide Inhalation Solution .02%, .5mg/2.5 ml, 30s | 49502-685-33 |
| Ipratropium Bromide Inhalation Solution .02%, .5mg/2.5ml, 60s | 49502-685-60 |
| Ipratropium Bromide Inhalation Solution .02%, .5mg/2.5 ml, 25s | 49502-685-03 |

30. Drug manufacturers, such as Dey, have not typically submitted claims for reimbursement to federal health care programs. Instead, Dey has marketed its products to its

customers, who then purchased the product either directly or through wholesalers based on a price the customers negotiated with Dey. In addition to using wholesalers, customers also purchase Dey products through group purchasing organizations ("GPO"), who negotiate prices on behalf of Dey's customers.

31. Dey's customers then submit claims for payment for Dey products to Medicare and Medicaid after dispensing or administering the Dey drug.

32. For the most part, in the Medicaid program, claims submitted by retail pharmacies are processed and tracked using the NDC of the drug.

33. The Medicare program generally uses the Healthcare Common Procedural Coding System ("HCPCS") to reimburse for drugs. The HCPCS utilizes 5-digit alphanumeric codes to identify and bill for medical products and supplies. The HCPCS code for the Dey drugs reimbursed by Medicare at issue here is J6744.

34. During the relevant period, Dey has usually reported prices to various price publishers and services on an annual basis. The price publishers used the information to publish pricing compendia.

35. The reimbursement amounts for claims submitted by Dey's customers were directly influenced by Dey's false price representations. The information contained in the published pricing compendia has been used by most third party payor insurance companies, including the Medicare program (through December 31, 2004) and Medicaid programs, in determining the reimbursement rates for prescription drugs. Dey documents show that Dey knew of the impact of its price representations on government reimbursement for claims submitted by its customers for Dey's drugs. Dey documents also show that the company

actively marketed the government-funded profits or "spreads" on its drugs created by its false price representations.

36. No governmental payor knew of or sanctioned Dey's conduct as set forth in this Complaint, i.e., its deliberate manipulation of its published prices for certain of its products to induce its customers to purchase those products.

**D. Medicaid Reimbursement Formulas**

37. When reimbursing for drugs, the State Medicaid programs' goal has been to pay an amount which, in the aggregate, reflects the lower of (1) the estimated acquisition cost ("EAC") of covered drugs, plus a reasonable dispensing fee, or (2) a provider's usual and customary charges to the general public. Federal regulations define "estimated acquisition cost" in part as "the agency's best estimate of the price generally and currently paid by providers for a drug . . . ." 42 C.F.R. § 447.301. To determine the EAC for a covered drug, State Medicaid programs are required to develop reimbursement formulas that must be approved by the Secretary of HHS. 42 C.F.R. §§ 447.331, 447.332, and 447.333 (2005).

38. While the specific reimbursement formulas vary from state to state, the various State Medicaid programs have generally reimbursed for each drug based on the lowest of (a) the EAC as set by the states, (b) the maximum allowable cost ("MAC") set by the state Pharmaceutical Reimbursement Boards, or (c) the providers' usual and customary charge. For multiple source drugs subject to a federal upper limit, states must in the aggregate not pay more than those limits. 42 C.F.R. §§ 447.331, 447.332 and 447.333 (2005).

39. The states' methodologies for arriving at EAC include:

A. discounting a percentage off of the Average Wholesale Price ("AWP");

B. adding a percentage to the Wholesale Acquisition Cost ("WAC") ; and/or,

C. requiring the drug companies to certify prices directly in writing to the Medicaid program in response to state requests for particular pricing information.

40. AWP is used to refer to the price at which a pharmaceutical firm or a wholesaler sells a drug to a retail Customer who then administers it to a patient. WAC is used to refer to the price at which a pharmaceutical firm typically sells a drug to wholesalers who would then resell it to a retail Customer.

41. While the majority of states have used published AWPs to calculate reimbursement, approximately six states (Alabama, Florida, Maryland, Massachusetts, Rhode Island, and Texas) have used the wholesale acquisition cost ("WAC") to set the EAC.

42. The AWPs and WACs relied upon by the State Medicaid programs have generally been those published by (1) Thomson Publishing, publisher of the *Red Book* and various other price publications, (2) First Databank, publisher of the *Blue Book* and other electronic price publications; or (3) Medi-Span, Inc., publisher of an electronic or automated price service and the Hospital Formulary Pricing Guide. Thompson Publishing, First Databank and Medi-Span, Inc. are hereafter referred to as the "Publishers" and their various publications and data services are hereinafter referred to as "Price Publications."

43. In addition to relying on the manufacturers' reported prices as published in the Price Publications, some State Medicaid programs also received price representations directly from manufacturers, and relied on these representations to confirm the accuracy of the figures they use to determine state reimbursement amounts.

44. Pursuant to section 6001 of the Deficit Reduction Act of 2005, Pub. L. 109-171, effective January 1, 2007, CMS is to provide States with "average manufacturer price" data which will give States additional drug price information.

**E. Medicare Reimbursement Formulas**

45. From 1992 through 1997, Medicare based its reimbursement for multi-source generic drugs, the drugs at issue here, at the lower of the EAC or the median AWP of all generic forms of a drug. 42 C.F.R. § 405.517 (1992-1998). In general, Medicare relied on median AWPs to set reimbursement rates.

46. From January 1, 1998, until December 31, 1998, Medicare based its reimbursement for all generic forms of a drug at 95% of the median AWP for the drug. Balanced Budget Act of 1997, 42 U.S.C. § 1395u(o).

47. From 1999 through 2003, Medicare reimbursed for Part B covered drugs at the lower of (a) 95% of the median published AWP for the drug; or (b) the AWP of the least expensive brand-name drug. 42 U.S.C. § 1395u(o); 42 C.F.R. § 405.517 (1999-2004). During 2004, Medicare reimbursed at a percentage of AWP dictated by statute, which, in the case of the drugs that are the subject of this complaint, was 80 percent. 42 C.F.R. § 414.707 (2005). For drugs furnished after January 1, 2005, reimbursement is no longer based on AWP but is generally based on average sales price. 42 C.F.R. § 414.904.

48. After the reimbursement amount is calculated, Medicare pays 80 percent and the Medicare beneficiary is responsible for the remaining 20 percent co-payment. If the Medicare beneficiary is also a Medicaid recipient, the Medicaid program generally pays the 20 percent Medicare co-payment.

49. Medicare generally relied upon the AWPs published by Thomson Publishing in its annual national compendium known as the Drug Topics Red Book ("Red Book"), as well as Red Book monthly updates to set reimbursement rates for covered drugs.

## VII. DEY'S SCHEME

50. From on or before December 31, 1992, and continuing through 2004 in the case of the Medicare program, and to the present in the case of the Medicaid program, Dey has knowingly caused the Medicare and Medicaid programs to pay false or fraudulent claims for the following respiratory therapy medications: albuterol sulfate, albuterol MDI, cromolyn sodium, and ipratropium bromide. As part of its unlawful conduct, Dey knowingly made false or fraudulent representations about drug prices and costs to the *Red Book*, First DataBank, and Medispan, while knowing that Medicare and Medicaid would use this information in paying or approving claims for such drugs. Dey further made these representations in order to use the "spread" between cost and reimbursement to induce purchasers to buy Dey's drugs.

51. To inflate the spread, and thereby induce purchases of its drugs, Dey purposely reported to the *Red Book*, First DataBank, and Medispan (and in some instances, the states) inflated AWPs and WACs for its drugs, while simultaneously arranging for its retail customers to purchase these drugs through wholesalers at far lower prices. The Medicare and Medicaid payments, made in response to claims submitted by Dey's customers, were set based on the inflated AWPs and WACs, and the payment amounts far exceeded the actual costs of the drugs.

52. When Dey prepared to launch its albuterol, cromolyn sodium, and ipratropium bromide products in 1992, 1993, and 1996, respectively, Dey established and reported its AWP with the specific purpose of creating an attractive spread between the AWP and the actual price,

so as to create an inducement–at the expense of the Medicare and Medicaid programs–for providers to purchase the Dey product.

53. For example, on February 24, 1992, senior marketing managers at Dey developed a pricing strategy for the upcoming launch of Dey's new generic albuterol product. Dey's Vice President for Sales and Marketing issued a memorandum to, among others, the President of Dey, stating that one of Dey's pricing objectives was to "[p]rovide an incentive to retail and chain pharmacies to purchase Dey's Albuterol unit dose by increasing the spread on Medicare/Medicaid reimbursements."

54. Similarly, in late 1995, when Dey prepared to launch its ipratropium products, Dey marketing personnel prepared a marketing plan that expressly included as the company's strategy to "Set price and AWP to enhance sales while maximizing customer loyalty." Dey used a similar strategy when it launched its cromolyn sodium product in 1993.

55. Dey's reported AWPs increasingly bore little or no relationship to the actual prices being paid by Dey's customers for the specified drugs. As a result, the spreads on Dey's drugs were large and exceeded 500% in some instances. Dey manipulated and controlled the size of the "spread" on its drugs by reporting inflated AWPs and WACs, while simultaneously decreasing its sales prices to wholesalers and providers. A chart setting out some examples showing the difference between the prices at which Dey actually sold its drugs and the false prices reported by Dey is attached hereto as Exhibit A.

56. For example, the AWP per unit for Dey's most popular albuterol sulfate solution stayed constant at $30.25 per unit from 1994 through 2002. Meanwhile, the actual sales price to customers such as Ven-A-Care steadily dropped, reaching a low of $3.70 in 2002. Likewise, the

AWP per unit for Dey's ipratropium inhalation solution (size 30s) stayed constant at $52.80 per unit from 1997 through 2002, while the sales price to customers such as Ven-A-Care decreased significantly, declining to $8.25 in 2002.

57. Dey trained its sales force on the significance of Medicare and Medicaid reimbursement and the importance of the "spread" between the AWP and the customer's actual cost. In order to induce customers to purchase Dey drugs, Dey sales personnel actively marketed the spread between the AWP and its customers' actual costs: Dey went so far as to create a "Reimbursement Comparison Worksheet" to show customers that, if they purchased Dey's version of a particular generic drug, they would receive greater net reimbursement than if they purchased a competitor's version of the same or similar drug.

58. Dey also reported falsely inflated WAC prices to the *Red Book*, First DataBank, and Medispan in order to create a spread in states that relied on WAC prices as a basis for Medicaid reimbursement.

59. On May 30, 1995, a senior Dey Marketing Manager informed Dey's Vice President for Sales and Marketing, along with Dey's entire sales and marketing force, that the WAC prices that Dey was transmitting to certain states were "*not representative of our published wholesale list prices, but like AWP, is used for calculation of reimbursement.*" (Emphasis added.) On that same day, Dey informed the pricing services of false, fraudulent and inflated AWPs and WACs for Dey's albuterol sulfate inhalation solution 0.083%.

60. Throughout the relevant time period, despite steadily reducing the prices it charged its customers, Dey did not update its AWP pricing information to any of the price

reporting services. Over time, Dey's AWPs bore little or no relation to the price actually charged to any customer.

61. As a result of Dey's conduct, pharmacists and other providers submitted thousands of claims to the Medicare and Medicaid programs and received millions of dollars in excessive reimbursement.

**FIRST CAUSE OF ACTION**

(False Claims Act: Presentation of False Claims)
(31 U.S.C. § 3729(a)(1))

62. The United States repeats and realleges paragraphs 1 through 61 as if fully set forth herein.

63. Dey knowingly caused to be presented false or fraudulent claims for payment or approval to the United States for the drugs listed in Paragraph 29 for reimbursement that was substantially higher than providers' actual acquisition costs for those drugs and based on reported prices that were fraudulently and artificially created and manipulated by Dey. Dey knowingly used the spread as an unlawful inducement in violation of the federal anti-kickback statute, causing resulting false and fraudulent claims to be submitted.

64. By virtue of the false or fraudulent claims that Dey caused to be made, the United States has suffered damages and therefore is entitled to treble damages under the False Claims Act, to be determined at trial, plus civil penalties of not less than $5,000 and up to $10,000 for each violation occurring before September 29, 1999, and not less than $5,500 and up to $11,000 for each violation occurring on or after September 29, 1999.

## SECOND CAUSE OF ACTION

(False Claims Act: Making or Using False Records or Statements to Cause Claims to be Paid)
(31 U.S.C. § 3729(a)(2))

65. The United States repeats and realleges paragraphs 1 through 61 as if fully set forth herein.

66. Dey knowingly made, used, or caused to be made or used, false records or statements to cause false or fraudulent claims paid or approved by the United States. The false records or statements consisted of the false certifications and representations made or caused to be made by Dey to state Medicaid programs when seeking to ensure that the Medicaid programs would reimburse for Dey' drugs, and the false representations to the pricing publishers and services upon which Medicare and Medicaid relied.

67. By virtue of the false records or false statements made by the Dey, the United States has suffered damages and therefore is entitled to treble damages under the False Claims Act, to be determined at trial, plus civil penalties of not less than $5,000 and up to $10,000 for each violation occurring before September 29, 1999, and not less than $5,500 and up to $11,000 for each violation occurring on or after September 29, 1999.

## THIRD CAUSE OF ACTION

(Unjust Enrichment)

68. The United States repeats and realleges paragraphs 1 through 61 as if fully set forth herein.

69. The United States claims the recovery of all monies by which Dey has been unjustly enriched, including profits earned by Dey because of illegal inducements Dey arranged to be paid to its customers.

70. By obtaining monies as a result of its violations of federal and state law, Dey was unjustly enriched, and is liable to account and pay such amounts, which are to be determined at trial, to the United States.

71. By this claim, the United States requests a full accounting of all revenues (and interest thereon) and costs incurred by Dey on sales to customers to whom it arranged for unlawful inducements, and disgorgement of all profits earned and/or imposition of a constructive trust in favor of the United States on those profits.

**FOURTH CAUSE OF ACTION**

(Common Law Fraud)

72. The United States repeats and realleges paragraphs 1 through 61 as if fully set forth herein.

73. Dey made material and false representations concerning the pricing of its drugs with knowledge of their falsity or with reckless disregard for the truth, with the intention that the United States act upon the misrepresentations to its detriment. The United States acted in justifiable reliance upon Dey' misrepresentations by making payments on the false claims.

74. Had Dey made truthful representations, the United States would not have made such payments.

75. By reason of these payments, the United States has been damaged in an as yet undetermined amount.

## PRAYER FOR RELIEF

WHEREFORE, the United States demands and prays that judgment be entered in its favor against Dey, Inc., Dey L.P., Inc., and Dey L.P., jointly and severally, as follows:

1. On the First and Second Causes of Action, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are required by law, together with all such further relief as may be just and proper.

2. On the Third Cause of Action, for the damages sustained and/or amounts by which Dey was unjustly enriched, including an accounting of all revenues unlawfully obtained by Dey, the imposition of a constructive trust upon such revenues, and the disgorgement of the illegal profits obtained by Dey, plus interest, costs, and expenses, and all such further relief as may be just and proper.

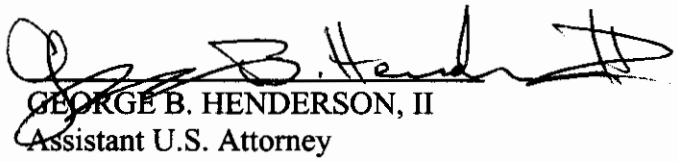
3. On the Fourth Cause of Action, for compensatory and punitive damages in an amount to be determined, together with costs and interest, and for all such further relief as may be just and proper.

DATED this 22d day of August, 2006.

Respectfully submitted,

PETER D. KEISLER
ASSISTANT ATTORNEY GENERAL

MICHAEL J. SULLIVAN
UNITED STATES ATTORNEY

By: 

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# Exhibit A
## Selected Dey AWPS, Actual Prices and Spreads

| DRUG/DOSAGE | NDC | YEAR* | RED BOOK AWP | FIRST DATABANK AWP | MEDISPAN AWP | PRICE TO PHARMACY CUSTOMER (VEN-A-CARE) | SPREAD (AWP less Price) | SPREAD % (Spread/Price) |
|---|---|---|---|---|---|---|---|---|
| Albuterol Inhalation Solution 0.5%, 20 ml | 49502-0105-01 | 2001 | $14.99 | $14.99 | $14.99 | $3.73 | $11.26 | 302% |
| Albuterol Inhalation Solution 0.5%, 20 ml | 49502-0196-20 | 1998 | $14.99 | $14.99 | NO DATA | $4.95 | $10.04 | 203% |
| Albuterol Inhalation Aerosol 17 gm (90 mcg Aerosol Inhaler) | 49502-0303-17 | 2000 | $21.70 | $21.70 | $21.70 | $3.09 | $18.61 | 602% |
| Albuterol Inhalation Aerosol (refill) 17 gm | 49502-0303-27 | 2000 | $19.79 | $19.79 | NO DATA | $2.98 | $16.81 | 564% |
| Albuterol Inhalation Aerosol 17 gm (90 mcg Aerosol Inhaler) | 49502-0333-17 | 2001 | $21.70 | $21.70 | $21.70 | $3.83 | $17.87 | 467% |
| Albuterol Sulfate 0.083% 3 ml, 25s | 49502-0697-03 | 2001 | $30.25 | $30.25 | $30.25 | $4.10 | $26.15 | 638% |
| Albuterol Sulfate 0.083% 3 ml, 30s | 49502-0697-33 | 2001 | $36.30 | $36.30 | $36.30 | $5.11 | $31.19 | 610% |
| Albuterol Sulfate 0.083% 3 ml 60s | 49502-0697-60 | 2001 | $72.60 | $72.60 | $72.60 | $9.95 | $62.65 | 630% |
| Ipratropium Bromide 0.02 % 2.5 ml, 25's | 49502-0685-03 | 2001 | $44.10 | $44.00 | $44.10 | $8.52 | $35.58 | 418% |
| Ipratropium Bromide 0.02 % 2.5 ml, 30's | 49502-0685-33 | 2001 | $52.80 | NO DATA | $52.80 | $10.22 | $42.58 | 417% |
| Ipratropium Bromide 0.02 % 2.5 ml, 60's | 49502-0685-60 | 2001 | $105.60 | $105.60 | $105.60 | $20.45 | $85.15 | 416% |
| Cromolyn Sodium 2 ml 60s | 49502-0689-02 | 2001 | $42.00 | $42.00 | $42.00 | $9.95 | $32.05 | 322% |
| Cromolyn Sodium 2 ml 120s | 49502-0689-12 | 2001 | $84.00 | $84.00 | $84.00 | $19.80 | $64.20 | 324% |

*Showing all drugs for 2001, or the last year if drug discontinued prior to 2001.